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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,241	11/12/2003	Alvin Kershman	45100/88023	6398

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EXAMINER	
WEBMAN, EDWARD J	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,241	KERSHMAN ET AL.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7,19-24 and 27* is/are pending in the application.

4a) Of the above claim(s) *8-18., 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7,19-24 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/22/07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The examiner adopts in part the rejection 10/425515 filed 8/18/05 as applied to the instant claims:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 7, 19-20, 22, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn, R. L. (U.S. patent 6,120,789).

Applicants' claims are drawn to a sustained release delivery system comprising at least one lipid, dry particles including at least one pharmaceutical that is at least partially microencapsulated, and at least one filler. The pharmaceutical agent is selected from the group consisting of analgesics, antibodies, anti-inflammatory agents, cardiovascular drugs, gastrointestinal medicines, hormones, and laxatives.

Dunn teaches a non-polymeric composition for in situ formation of a solid matrix in an animal, and use of the composition as a medical device or as a sustained release delivery system for a biologically-active agent, among other uses (column 2, lines 41-45). This composition can also be used orally to treat periodontal disease (abstract).

Dunn states that his non-polymeric composition eventually forms a solid structure (column 2, lines 54-55) and that, alternatively, it can be formed into a solid implant outside of the body of an animal and then inserted as a solid matrix into the implant site (column 12, lines 53-55).

Dunn teaches that the non-polymeric materials useful in his compositions are those

that are biocompatible, substantially insoluble in water and body fluids, and biodegradable and/or bioerodible within the body of an animal. The non-polymeric material is capable of being at least partially solubilized in a water-soluble organic solvent. The non-polymeric materials are also capable of coagulating or solidifying to form a solid implant matrix upon the dissipation, disbursement or leaching of the solvent component from the composition and contact of the non-polymeric material with an aqueous medium. The solid matrix has a firm consistency ranging from gelatinous to impressionable and moldable, to a hard, dense solid (column 4, lines 34-46).

Dunn teaches examples of non-polymeric materials usable in his compositions, many of which are considered to be lipids. Examples of these materials are: sterols; cholesteryl; C12 -C24 fatty acids (e.g. lauric acid, myristic acid, palmitic acid, etc.); C18-C36 mono-, di- and triacylglycerides and mixtures thereof; sucrose fatty acid esters; sorbitan fatty acid esters; C~6 -C~8 fatty alcohols; esters of fatty alcohols and fatty acids; anhydrides of fatty acids; phospholipids including phosphatidylcholine (lecithin), phosphatidylserine, phosphatidylethanolamine, phosphatidylinositol, and lysoderivatives thereof; sphingosine and derivatives thereof; spingomyelins; ceramides; glycosphingolipids; lanolin and lanolin alcohols; and combinations and mixtures thereof (column 4, lines 47-67 and column 5, lines 1-12). In addition to being a lipid, lecithin can function as a surfactant (Myerson, R. M. Better Nutrition, (1989-1990), Oct. 1989).

Dunn teaches the inclusion of pore forming agents in his composition such as sugars, salts, and polymers, such as hydroxypropylcellulose, carboxymethylcellulose, polyethylene glycol and polyvinylpyrrolidone, and the like (column 7, lines 20-25). These

pore-forming agents can also function as fillers, because fillers are used to provide bulk to a pharmaceutical composition (cf. Remington's Pharmaceutical Sciences, A. R. Gennaro, Ed. Mack Publishing Company: Easton, PA 1990, p 1452).

Dunn teaches that examples of biologically active agents useful in his invention can include the following: anti-inflammatory agents, immunogens (vaccines) for stimulating antibodies; hormones, including testosterone; cardiovascular agents; anti-ulcer agents; etc., and other examples are incorporated by reference from U. S. patent 5,324,519 (column 9, lines 12-67, in particular, line 50).

Dunn teaches that his composition can also include a controlled release component associated with the active agent to control its release from the composition during formation of the implant and/or from the formed implant. A microcapsule is an example of several controlled release components taught by Dunn, see column 3, lines 8-14.

Dunn teaches that one or more modes of release controlling component can be used. The controlled release component can be, for example, a microstructure ranging in size from about 10 nm to about 500 microns, preferably less than about 150 microns, such as a microcapsule, microparticle such as a liposphere or microsphere, a nanoparticle, liposome, micelle, cage compound such as cyclodextrin, and the like; a macrostructure which size is larger than 500 microns, such as a fiber, film, rod, disc, cylinder, bead, and the like, including a reservoir system containing the active agent within a membrane, or a monolithic system with the active agent distributed throughout a matrix; and/or a low water-solubility salt of the active agent (solubility of 25 mg/l or less, 40 °C, 4 hours) that includes, for example, a carboxylate anion as a counterion for

the active agent (column 11, lines 18-36). The above physical dimensions of the controlled release component containing a pharmaceutical agent (bioactive agent) are all in the micrometer range (micron is synonymous with micrometer), and therefore these compositions could be considered microcapsules (i.e. the drug is microencapsulated).

Dunn states that the biologically-active agent is preferably soluble or dispersible in the non-polymeric composition to form a homogeneous mixture, and upon implantation, becomes incorporated into the implant matrix. As the solid matrix degrades over time, the biologically-active agent is capable of being released from the matrix into the adjacent tissue fluid, and to the pertinent body tissue or organ, either adjacent to or distant from the implant site, preferably at a controlled rate. The release of the biologically-active agent from the matrix may be varied, for example, by the solubility of the biologically-active agent in an aqueous medium, the distribution of the agent within the matrix, the size, shape, porosity, and solubility and biodegradability of the solid matrix (column 8, lines 47-60).

As to the claimed properties, they must be possessed by the anticipatory composition because it is the same as that claimed. As to the method limitations, they are not considered patentable in composition claims during prosecution before the USPTO.

Applicants argue that Dunn doesn't teach oral delivery. However, oral delivery is merely an intended use. Intended uses are not considered patentable limitations during prosecution of composition claims before the USPTO. As to applicants' arguments of

unexpected result and long felt need, such arguments are not germaine to a rejection under 35 USC 102.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 5, 7, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. (U.S. patent application, 2002/0012675).

Applicants' claims are drawn to a sustained release delivery system comprising at least one lipid, dry particles including at least one pharmaceutical that is at least partially microencapsulated, and at least one filler (e.g. a rupturing agent, such as sodium starch glycolate). The pharmaceutical agent is selected from the group consisting of analgesics, antibodies, anti-inflammatory agents, cardiovascular drugs, gastrointestinal medicines, hormones, and laxatives.

Jain teaches controlled release compositions that provide for the effective release of an incorporated drug or other substance in a patient for a time period ranging from about 2 to about 24 hours or longer (paragraph 0013).

Jain teaches that the compositions are comprised of nanoparticulate drug or other agent to be administered and that the effective average size of the particles, prior to inclusion, is less than about 1000 nm (paragraph 0014, 1st sentence). Particles having sizes of the order of -1000 nm are micrometer sized (1000 nm = 1 um).

Jain teaches that the composition also comprises at least one surface stabilizer associated with the surface of the nanoparticulate drug or other agent (paragraph 0014, 2nd sentence).

Jain teaches that his present invention can be provided in various dosages forms including oral, rectal, buccal, and vaginal. These dosage forms may be administered via tablets or multiparticulate forms.

Jain teaches that the drug can be selected from a variety of known classes of drugs, including for example, analgesics, anti-inflammatory agents, corticosteroids, parasympathomimetics, hormones, sex hormones (including steroids), and sympathomimetics, (paragraph 45).

Jain teaches suitable surface stabilizers are excipients that can preferably be selected from known organic and inorganic pharmaceutical excipients and include various polymers, low molecular weight oligomers, natural products, and surfactants. Lecithin, a phosphatide, is one of many examples of surface stabilizers taught by Jain. Phosphatides are a kind of lipid. In this context, lipid surface stabilizers, such as lecithin, are considered a coating on top of the nanoparticulate drugs used in Jain's invention (paragraph 0049).

Jain teaches other examples of surface stabilizers, and these are found in paragraph 0050.

Jain teaches the use of other pharmaceutical excipients in his compositions such as binding agents, diluents, lubricating agents, plasticisers, anti-tack agent, opacifying

agents, suspending agents, sweeteners, flavoring agents, preservatives, buffers, wetting agents, disintegrants, and pigments (paragraph 0057).

Jain teaches that suitable disintegrants include lightly crosslinked polyvinyl pyrrolidone, corn starch, potato starch, maize starch, and modified starches, croscarmellose sodium, cross-povidone, sodium starch glycolate, and mixtures thereof (paragraph 0063).

It would have been obvious to one of ordinary skill in the art to make a composition to deliver a microencapsulated hormone to achieve the beneficial effect of controlled release in view of Jain. As to the claimed testosterone, the examiner takes notice under MPEP 2144.03 that it well-known in the art as a hormone, useful, for example, in hormone replacement therapy. Thus, it would have been further obvious to add testosterone to the composition of Jain to achieve the beneficial effect of a hormone replacement delivery vehicle.

The argument regarding the claimed properties and method limitations in the first rejection is incorporated herein as applied to the instant rejection.

Applicants argue that Jain teaches a tablet whereas applicants claim a suspension. However, Jain also teaches rectal and vaginal routes (paragraphs 17, 25, and 85). Soft gelatin capsules are specified (paragraphs 23 and 70). It is argued that one of ordinary skill would configure the Jain composition to possess a hardness, for purposes of rectal and vaginal administration, like that of a suppository.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5, 7. 19-24, 26-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12-19, 21 of U.S. Patent No 6,541,025. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims encompass the scope of the instant claims regarding the nature of the claimed pharmaceutical.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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